



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

MAY 8 2001

Re: MiniMed 2007  
Docket No.: 00E-1608

The Honorable Q. Todd Dickinson  
Director of U.S. Patent and Trademark Office  
Commissioner for Patents  
Box Pat. Ext.  
Washington, D.C. 20231

#48

Dear Director Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 4,373,527, filed by the Johns Hopkins University, under 35 U.S.C. section 156. The device claimed by the patent is the MiniMed 2007. Your March 27, 2000 letter to us states that the subject patent would be eligible for extension of the patent term under 35 U.S.C. section 156(d)(5) only if an application under section 515 of the Federal Food, Drug, and Cosmetic Act was initially submitted prior to January 28, 2000, for the MiniMed 2007.

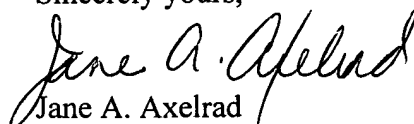
MiniMed Technologies submitted a Premarket Approval Application (PMA) for the MiniMed 2007 on August 6, 1991. A PMA is an application submitted under section 515 of the Federal Food, Drug, and Cosmetic Act. The PMA for the MiniMed 2007 was assigned No. P910047. However, in a letter dated September 30, 1991, the FDA informed MiniMed Technologies that PMA P910047 was not filed by the agency because it was incomplete. On March 20, 1992, MiniMed Technologies formally withdrew PMA P910047.

On July 12, 2000, MiniMed Technologies submitted the first part of a modular (partial) PMA for the MiniMed 2007. This is currently being reviewed by the agency's Center for Devices and Radiological Health.

Whether an application was initially submitted prior to January 28, 2000, under this set of facts, is a matter of interpretation that we will leave to the Patent and Trademark office to determine, using the dates we have provided in this letter as the basis for that interpretation.

Please let me know if we can be of further assistance.

Sincerely yours,

  
Jane A. Axelrad

Associate Director for Policy  
Center for Drug Evaluation and Research